



3510-16-P

## DEPARTMENT OF COMMERCE

### United States Patent and Trademark Office

#### Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures

**ACTION:** Proposed collection; comment request.

**SUMMARY:** The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on this proposed extension of an existing information collection.

**DATES:** Written comments must be submitted on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Written comments may be submitted by any of the following methods:

- *Email:* [InformationCollection@uspto.gov](mailto:InformationCollection@uspto.gov). Include "0651-0024 comment" in the subject line of the message.
- *Federal Rulemaking Portal:* <http://www.regulations.gov>.

- *Mail:* Marcie Lovett, Chief, Records and Information Governance Branch, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-7728; or by e-mail at Raul.Tamayo@uspto.gov with “0651-0024 comment” in the subject line. Additional information about this collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

## **SUPPLEMENTARY INFORMATION:**

### **I. Abstract**

Patent applications that contain nucleotide and/or amino acid sequence disclosures that fall within the definitions of 37 CFR 1.821(a) must include, as a separate part of the application disclosure, a copy of the sequence listing in accordance with the requirements in 37 CFR 1.821-1.825. Applicants may submit sequence listings for both U.S. and international patent applications. Submissions of sequence listings in international applications are in accordance with Patent Cooperation Treaty (PCT) Rules 5.2 and 13*ter*, as well as the PCT Administrative Instructions, Annex C.

This information collection covers the submission of the sequence listing information itself. Information pertaining to the filing of the initial U.S. application is collected under

OMB Control Number 0651-0032, and information pertaining to the filing of the initial international application is collected under OMB Control Number 0651-0021.

In particular, this information collection accounts for sequence listings submitted on paper, compact disc (CD), or through EFS-Web, the USPTO's online filing system. Sequence listings may be submitted via EFS-Web as an ASCII text file or in Portable Document Format (PDF). For U.S. applications, § 1.821(c) permits all modes of submission: paper, CD, or EFS-Web. Sequence listings for international applications may be submitted on paper or through EFS-Web only, though sequence listings that are too large to be filed electronically through EFS-Web may be submitted on CD.

This information collection also accounts for the requirement under § 1.821(e) that a copy of the sequence listing required by § 1.821(c) be submitted in computer readable form (CRF) in accordance with the requirements of § 1.824. Under §§ 1.821(e)-(f), applicants who submit their sequence listings on paper, CD, or as a PDF via EFS-Web must submit a copy of the sequence listing in CRF with a statement indicating that the CRF copy of the sequence listing is identical to the paper, CD, or PDF copy provided under § 1.821(c). Applicants may submit the CRF copy of the sequence listing to the USPTO on CD or other acceptable media as provided in § 1.824. If a new application is filed via EFS-Web with an ASCII text file sequence listing that complies with the requirements of §§ 1.824(a)(2)-(6) and (b), and applicant has not filed a sequence listing on paper, CD or as a PDF file, the text file will serve as both the copy required by § 1.821(c) and the CRF required by § 1.821(e). Moreover, the associated statement of identity would not be required.

This information collection also covers the mechanism in § 1.821(e) where an applicant may request, in limited circumstances, a transfer of the CRF from the application already on file to the new application, if the CRF sequence listing in a new application is identical to the CRF sequence listing of another application that the applicant already has on file at the USPTO. In such a case, the applicant may submit a letter identifying the application and CRF sequence listing that is already on file and stating that the sequence listing submitted in the new application is identical to the CRF copy already filed with the previous application. The USPTO provides a form, Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93), in order to assist customers in submitting this statement.

The USPTO uses the sequence listings during the examination process to determine the patentability of the associated patent application. The information in CRF is entered into the USPTO's database for searching and printing nucleotide and amino acid sequences. Sequence listings also are disclosed as part of the published patent application or issued patent and are provided to the National Center for Biotechnology Information (NCBI) for inclusion in their sequence database.

## **II. Method of Collection**

By mail, hand delivery, or electronic submission to the USPTO.

## **III. Data**

*OMB Number:* 0651–0024.

*Type of Review:* Revision of a currently approved collection.

*Affected Public:* Individuals or households; business or other for-profit organizations; and not-for-profit organizations.

*Estimated Number of Respondents:* 28,850 responses per year. Of this total, the USPTO expects that 25% will be from small entities.

*Estimated Time per Response:* The USPTO estimates that it will take approximately 6 minutes (0.10 hours) to 6 hours to complete a single IC item in this collection, depending on the instrument. This includes the time to gather the necessary information, create the documents, and submit the completed request to the USPTO.

*Estimated Total Annual Respondent Burden Hours:* 163,955 hours.

*Estimated Total Annual Respondent (Hourly) Cost Burden:* \$31,771,829.00. The USPTO estimates that a sequence listing will take approximately five hours of paraprofessional time at an estimated rate of \$145 per hour and one hour of attorney time at \$438 per hour, for a weighted average rate of \$193.83 per hour for preparing a sequence listing. These rates are found in the 2017 Report of the Economic Survey of the America Intellectual Property Law Association (AIPLA). The USPTO expects that the Request for Transfer of a CRF will be prepared by a paraprofessional at an estimated rate of \$145 per hour. Using this hourly rate, the USPTO estimates \$31,771,829.00 per year for the total hourly costs associated with respondents.

**Table 1: Burden Hour/Burden Cost to Respondents**

IC Number	Item	Estimated Response Time (Hours) (a)	Estimated Annual Responses (b)	Estimated Annual Burden Hours (a) x (b) = (c)	Rate (\$/hr) (d)	Total Cost (\$/yr) (c) x (d) = (e)
1	Sequence Listing in Application (paper)	6.00	5,000	30,000	\$193.83	\$5,814,900.00

1	Sequence Listing in Application (CD)	6.00	300	1,800	\$193.83	\$348,894.00
1	Sequence Listing in Application (electronic)	6.00	22,000	132,000	\$193.83	\$25,585,560.00
2	Request for Transfer of a Computer Readable Form Under 37 CFR 1.821(e) (PTO/SB/93)	0.10	1,550	155	\$145.00	\$22,475.00
	<b>Totals</b>	- - -	<b>28,850</b>	<b>163,955</b>	- - -	<b>\$31,771,829.00</b>

*Estimated Total Annual (Non-hour) Respondent Cost Burden: \$1,774,500.00.* This collection has no capital startup, maintenance, or operating fees. This collection does have a non-hourly cost burden in the form of filing fees and postage costs.

### Filing Fees

In accordance with 35 U.S.C. § 41(a)(1)(G), the USPTO charges a fee for submitting a sequence listing as part of a U.S. application or as part of an international application entering the U.S. national stage if the sequence listing (i) is not filed via EFS-Web or not filed on an electronic medium in compliance with §§ 1.52(e) and 1.821(c) or (e), and (ii) causes the application to exceed 100 pages. (See 37 CFR 1.52(f)). Under 37 CFR 1.16(s) and 1.492(j) for U.S. applications and international applications entering the U.S. national stage, respectively, if the application, including the sequence listings filed on paper or on a non-compliant electronic medium, exceeds 100 pages, the application size fee is \$400 (or \$200 for small entities and \$100 for micro entities) for each additional 50 pages or fraction thereof. The USPTO estimates the following with respect to the number of applications that will include long sequence listings filed on paper or on a non-compliant electronic medium and the average application size fee that such applications will incur: (i) approximately 160 applications from large entities will incur an average application size fee of \$1,200; (ii) approximately 80 applications from small entities will incur an average application size fee of \$600; and (iii) approximately 32

applications from micro entities will incur an average application size fee of \$300. The estimate corresponds to a total fee cost of \$240,000, \$60,000, and \$12,000, respectively.

As a Receiving Office, the USPTO collects the international filing fee for each international application it receives. The basic international filing fee only covers the first 30 pages of the international application. As a result, a \$15 fee per page is added to the international filing fee for each page over 30 pages of an international application including a sequence listing filed on paper or in PDF format. No page fees are triggered by sequence listings that are submitted via EFS-Web in the proper text format. The average length of a sequence listing filed on paper or in PDF format in an international application is 150 pages, which would carry an additional fee of \$2,250 if the international application were already at least 30 pages long without the listing. The USPTO estimates that approximately 520 of the 6,000 sequence listings filed per year on paper or in PDF format will be for international applications.

The USPTO charges a fee for the handling of mega sequence listings, i.e., sequence listings of 300 MB or more. Pricing for this fee is divided into two tiers with Tier 1 for file sizes 300 MB to 800 MB and Tier 2 for file sizes greater than 800 MB. The USPTO also charges a fee, i.e., the Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13<sup>ter</sup>, to encourage timely filing of sequence listings in international applications and to facilitate the effective administration of the patent system.

**Table 2: Filing Fee Costs**

IC	Item	Estimated Annual	Fee Amount	Total Fees
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Number		Responses (a)	(b)	(a) x (b) = (c)
1	Size fees under 37 CFR 1.16(s) and 1.492(j), large entity	160	\$1,200.00	\$192,000.00
1	Size fees under 37 CFR 1.16(s) and 1.492(j), small entity	80	\$600.00	\$48,000.00
1	Size fees under 37 CFR 1.16(s) and 1.492(j), micro entity	32	\$300.00	\$9,600.00
1	Size fees for international applications	520	\$2,250.00	\$1,170,000.00
1	Submission of sequence listings of 300MB to 800MB (large entity)	20	\$1,000.00	\$20,000.00
1	Submission of sequence listings of 300MB to 800MB (small entity)	13	\$500.00	\$6,500.00
1	Submission of sequence listings of 300MB to 800MB (micro entity)	2	\$250.00	\$500.00
1	Submission of sequence listings of more than 800MB (large entity)	1	\$10,000.00	\$10,000.00
1	Submission of sequence listings of more than 800MB (small entity)	1	\$5,000.00	\$5,000.00
1	Submission of sequence listings of more than 800MB (micro entity)	1	\$2,500.00	\$2,500.00
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (large entity)	91	\$300.00	\$27,300.00
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (small entity)	312	\$150.00	\$46,800.00
1	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13ter (micro entity)	3	\$75.00	\$225.00
	<b>Totals</b>	<b>28,536</b>	<b>- - -</b>	<b>\$1,538,425.00</b>

Therefore, the USPTO estimates that the total fee costs for this collection will total \$1,538,425.00.

#### Postage Costs

Mailed submissions may include the sequence listing on either paper or CD, the CRF copy of the listing on CD, and a transmittal letter containing the required identifying information. The USPTO estimates that the average postage cost for a paper or CD



sequence listing submission will be \$6.55 (USPS Priority Mail, flat rate envelope) and that 5,300 sequence listings will be mailed to the USPTO per year, for a total of \$34,715.00 in postage costs.

With filing fee costs totaling \$1,538,425.00 and postage costs totaling \$34,715.00, the USPTO estimates that the total annual non-hourly cost burden for this collection will amount to \$1,573,140.00.

#### **IV. Request for Comments**

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Comments are invited on:

- (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
- (b) The accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Marcie Lovett,

Chief, Records and Information Governance Branch,

Office of the Chief Administrative Officer,

United States Patent and Trademark Office.

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